

## **Key Medical Antibiotics in Veterinary/Human Medicine to Become “Prescription Only” in June 2023**

In June 2023, the Food and Drug Administration (FDA) Center for Veterinary Medicine (CVM) will implement the Guidance for Industry (GFI) #263. This guidance instructs animal drug companies to voluntarily change labels for certain antibiotics that are medically important for human medicine and currently available over-the-counter for animals. This label change will require a prescription to be obtained from a licensed veterinarian for legal use of the antibiotics.

Previously, a veterinary prescription was required only for some injectable products as well as for antibiotics used in feed and water. GFI #263 extends this requirement to cover all antibiotics administered through any route. By requiring veterinary oversight over all medically important antibiotics, the FDA is taking a critical step in strengthening antibiotic stewardship and protecting public health against the growing threat of antibiotic resistance. Antimicrobial resistance (AMR), is a serious threat to animal and public health. Antimicrobial use in humans, animals, and horticulture can contribute to the development of antimicrobial resistance. Using antimicrobials wisely, in all settings, can help slow the rate at which AMR develops.

Antibiotics are drugs that fight infections caused by bacteria NOT viruses. Antibiotics are not effective against viral infections like Infectious bovine rhinotracheitis (IBR), Bovine Viral Diarrhea (BVD) and Bovine Respiratory Syncytial Virus (BRSV), which are part of the “shipping fever” complex in cattle. While some healthcare tasks can be performed by producers, a veterinarian is an invaluable partner in properly diagnosing and treating illness and infection. Because antibiotics become less effective the more they are improperly used, public backing for expanded veterinary oversight helps ensure that these lifesaving drugs are used justly in every setting. Strong public support for the new policy—which will be fully implemented June 11, 2023—demonstrates continued interest in FDA efforts to combat the emergence of superbugs. FDA received more than 5,000 positive comments from people urging swift finalization and implementation of the requirement. Antibiotics are a powerful tool for both human and animal health and can remain effective through responsible antibiotic stewardship.

**What is antibiotic stewardship?** Responsible stewardship practices include actions that preserve the effectiveness of antibiotics while maintaining animal health, such as:

- Only using antibiotics when necessary to manage illness in animals
- Establishing best management practices, like use of vaccines, and disease prevention plans to reduce the overall need for antibiotics
- Livestock owners and veterinarians working together to make decisions that improve animal health and welfare long-term

**Why would I need to consult a veterinarian to get the same drugs I have always used?**

Due to veterinarians’ specialized training and experience, obtaining these drugs under their supervision can help guide the accurate use of antimicrobials and slow the development of antimicrobial resistance. Sometimes antimicrobial drugs may not be necessary for proper

treatment or a different drug may be a better tool than the one you are used to using. Providing animals with the most appropriate antimicrobial is more likely to effectively resolve the infection and reduce the need for repeated or extended courses of antimicrobial therapy. This will not only help to reduce AMR risks but will help to ensure better health outcomes for animals and can also save time and money.

### **How will farmers and ranchers continue to get access to the antimicrobials they need for sick animals?**

After animal drug manufacturers and distributors make the changes recommended in GFI #263, farmers and ranchers would still have access to appropriate antimicrobials to address animal health issues by consulting with a licensed veterinarian with whom they have established a valid veterinarian-client-patient relationship (VCPR). Just because a drug has prescription status does not necessarily mean you are required to purchase it directly from a veterinarian. Although certain state requirements may also apply, you may be able to purchase prescription animal drug products from various suppliers or distributors with a valid prescription provided by a licensed veterinarian.

### **What are examples of drugs needing prescription?**

- Cephapirin, Cephapirin Benthazine (mastitis treatment tubes)
- Oxytetracycline (Example: LA 200 or LA 300)
- Penicillin G Procraine, Penicillin G Benzathine
- Sulfadimethoxine (Example: sulfa boluses for foot rot and diarrhea in calves)
- Tylosin

### **What is a valid veterinarian-client-patient relationship (VCPR)?**

A valid "Veterinarian-client-patient relationship" means that (1) the veterinarian has assumed the responsibility for making clinical judgments regarding the health of the animal and the need for medical treatment, and the client has agreed to follow the veterinarian's instructions; and (2) The veterinarian has sufficient knowledge of the animal to initiate at least a general or preliminary diagnosis of the medical condition of the animal because the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal either by examination of the animal or by medically appropriate and timely visits to the premises where the animal is kept.

### **How do I establish a VCPR with a veterinarian?**

The best time to talk to your veterinarian is before your animals get sick to ensure you have the right antibiotic for your animals when they need them.

1. **Find a Veterinarian.** Identify a veterinarian as a partner in supporting your livestock's health. By having a veterinarian who is familiar with you and your livestock, they can be prepared to provide appropriate care in the case of an illness or infection.

### Questions to ask your veterinarian:

- What do we need to do to establish and maintain a valid veterinarian-client-patient relationship (VCPR)?
  - What should my treatment records include?
  - What illnesses and conditions should we establish a protocol for?
  - How can I improve antibiotic stewardship on my operation?
  - How will I get a prescription for an antibiotic?
2. **Build a VCPR** A valid veterinarian-client-patient relationship (VCPR) is required for extra-label drug use. Working with a veterinarian to make a plan will allow them to determine when antibiotics can reduce the need for extra veterinary visits and help expedite treatments for your livestock.
  3. **Schedule Routine Visits** Routine visits are more cost-effective and encourage a preventative and proactive approach to maintaining your livestock's health.
  4. **Set Treatment Protocols** Before illness occurs, set protocols for common conditions with your veterinarian so that you have access to the antibiotics needed to take swift action on your own and recognize when you need to involve your vet.

### What information must be included on the label of the prescription animal drug?

- Name and address of the dispenser,
- Serial number and date of the order or its filling,
- Name and address of the veterinarian who prescribed or ordered the drug product,
- directions for use, and
- Any necessary warning and precautionary statements including withdrawal times.

Veterinarians must include the appropriate applicable information (above) in their prescription to allow it to be dispensed. Veterinarians must also follow State laws for dispensing animal drugs.

Veterinarians should make efforts to ensure their instructions are followed, especially when they prescribe or recommend drugs for food-producing animals that require a withdrawal period.

For further information call the State Veterinarian, Jim Watson, DVM, at (888) 646-8731.